18, this amendment is believed to be non-narrowing. Applicant respectfully requests withdrawal of this rejection.

The rejection asserts that claims 22, 25, and 26 lack antecedent basis for "the lowpass filter." Accordingly, Applicant has amended claim 21 to recite "the lowpass filter" instead of the "lowpass filter module," to clarify the antecedent basis for this term in claims 22, 25, and 26. Because this amendment merely provides antecedent basis for an existing claim term, Applicant submits that this amendment is non-narrowing. Applicant respectfully requests withdrawal of this rejection.

The rejection asserts that claim 29 lacks antecedent basis for "the thoracic fluid shift." Accordingly, Applicant has amended claim 29 to recite "the thoracic fluid shift signal," for which antecedent basis exists in claim 29. Because this amendment merely provides antecedent basis for an existing claim term, Applicant submits that this amendment is non-narrowing. Applicant respectfully requests withdrawal of this rejection.

§102 Rejection of the Claims

1. Claims 1 – 12 and 15 – 30 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yerich et al. (U.S. Patent No. 5,562,711). Applicant traverses.

Claim 1 has been cancelled, thereby mooting this rejection of claim 1.

Claim 2 has been amended into independent form. Therefore, claim 2 now expressly incorporates all the limitations of claim 1, from which it previously was dependent. Claim 2 also includes other amendments.

Yerich et al. is apparently directed toward a cardiac pacemaker providing a rate response using the patient's level of physical activity and the patient's minute ventilation. By contrast, Applicant can find no disclosure in Yerich et al. of providing a therapy to the subject's heart based at least in part on the baseline detected thoracic impedance associated with a fluid shift away from the thorax, as presently recited or incorporated into claims 2-3 and 5-8.

The rejection asserts that "it is inherent changes in tidal volume are impacted by fluid shifting to and from the lungs." (*See* Office Action ¶ 3.) Applicant disagrees with this assertion. Applicant can find no such express or inherent disclosure in Yerich et al. To the extent that this assertion relies on the Examiner's personal knowledge, Applicant objects to any such reliance on

Official Notice and respectfully requests a reference supporting such a teaching or suggestion. *See* M.P.E.P. § 2144.03. Moreover, even if support for such an assertion could be found in such a reference, it still fails to disclose providing a therapy using a detected baseline thoracic impedance associated with a fluid shift away from the thorax. Because the rejection using Yerich et al. does not disclose all elements of claims 2-3 and 5-8, Applicant respectfully requests withdrawal of this rejection of these claims.

Claim 4 has been amended into independent form. Therefore, claim 4 now expressly incorporates all the limitations of claim 1, from which it previously depended. Because this amendment of claim 4 merely expressly incorporates limitations that were previously inherent by the prior dependency from claim 1, Applicant submits that this amendment is non-narrowing. Applicant can find no disclosure in Yerich et al. of increasing a rate of pacing stimuli based at least in part on an increase in the baseline portion of the thoracic impedance, as recited or incorporated in claims 4 and 9-12.

The specification of the present patent application expressly distinguishes the "baseline portion" of the thoracic impedance from other higher frequency components of the thoracic impedance that are substantially influenced by the patient's breathing. (*See* Application at page 9, lines 2 – 14). The rejection itself recognizes that Yerich et al. discloses only measuring these higher frequency components of thoracic impedance:

> The lowpass filtering of the impedance signal yields the respiratory rate while the highpass filtering of the same signal yields the patient's cardiac function . . . The low-pass filter *has a bandpass* of 0.05 to 0.8 Hz.

(Office Action ¶ 3.) Because the bandpass filtering of Yerich et al. intentionally attenuates the baseline thoracic impedance referred to in claims 4 and 9-12, Yerich et al. actually teaches away from the subject matter recited in that claim. Moreover, not only can Applicant find no disclosure in Yerich et al. of using the baseline portion of the thoracic impedance, Applicant further cannot find any disclosure using an increase in the baseline portion of the thoracic impedance. Accordingly, Applicant respectfully requests withdrawal of this rejection of claims 4 and 9-12.

Similarly, Applicant can find no disclosure in Yerich et al. of the language recited or incorporated in:

- claims 15-16, of an averager/lowpass filter that obtains a baseline portion of the thoracic impedance signal that is associated with a fluid shift away from the thorax;
- claim 17, of a means for performing the function of obtaining a baseline portion of the thoracic impedance signal that is associated with a fluid shift away from the thorax;
- claims 18-28, of adjusting the rate of delivery of pacing stimuli based at least in part on the baseline portion of the thoracic impedance signal associated with the thoracic fluid shift away from the thorax;
- claim 29, of a lowpass filter for distinguishing a baseline thoracic fluid shift signal from another variation in thoracic impedance, and adjusting the rate of delivery of pacing stimuli based at least in part on the thoracic fluid shift; and
- claim 30, of adjusting a rate of delivery of pacing stimuli based at least in part on a baseline portion of the thoracic impedance associated with a thoracic fluid shift.

Instead, as discussed above, Yerich et al. actually teaches away from using such a thoracic fluid shift by attenuating baseline portions of the thoracic impedance signal at lower frequencies than the respiration signal used by Yerich et al. Accordingly, Applicant respectfully requests withdrawal of this rejection of claims 15-30.

2. Claims 1 – 3, 5 - 6, 8, 13 and 15 - 17 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Combs et al. (U.S. Patent No. 5,957,861). Applicant traverses. Claim 1 has been cancelled, thereby mooting this rejection of that claim. However, Applicant can find no disclosure in Combs et al. of the language recited or incorporated in:

- claims 2-3, 5-6, and 8, of providing a therapy to the subject's heart based at least in part on the detected baseline thoracic impedance associated with a fluid shift away from the thorax;
- claim 13, of detecting both a hypotension associated with a change in a subject's posture and a hypotension that is not associated with a change in the subject's posture, and providing a therapy to the subject's heart based at least in part on the detected hypotension;
- claims 15-16, of an averager/lowpass filter that obtains a baseline portion of the thoracic impedance signal that is associated with a fluid shift away from the thorax; and

- claim 17, of a means for performing the function of obtaining a baseline portion of the thoracic impedance signal that is associated with a fluid shift away from the thorax.

Instead, as the rejection acknowledges, Combs et al. is directed toward discerning edema by evaluating respiratory rate. However, as discussed above, with respect to Yerich et al., the present application distinguishes between baseline thoracic impedance, which is associated with fluid shift away from the thorax, and the higher frequency component of thoracic impedance that is associated with respiratory rate. Therefore, by using the respiratory rate component of thoracic impedance instead of the fluid shift component of thoracic impedance, Combs et al. actually teaches away from the subject matter recited in claims 1 – 3, 5 - 6, 8, 13 and 15 – 17.

The rejection also asserts that, in Combs et al., "edema in the lungs is noted to impact blood pressure, hence creating hypotension when the pressure is low and hypertension when the pressure is high; abnormal blood pressure may be treated by drugs (c 8, ll 37-48.)" (Office Action ¶ 4.) Applicant traverses this assertion that Combs et al. discloses that edema impacts blood pressure. The cited portion of Combs et al. states:

> if the edema level has changed greatly within a short period of time and the pressure values confirm that there is a physiologic problem, a drug pump can add diuretic as well as blood pressure medicaments to the patient's body automatically, whereas if the blood pressure has not increased, only the diuretic can be added.

(Combs et al. at column 8, lines 41-46.) This passage fails to disclose that edema impacts blood pressure. Instead, it apparently merely notes that edema and blood pressure can be separately treated by a diuretic and blood pressure medicaments, respectively.

In sum, Applicant respectfully submits that Combs et al. fails to disclose all elements of the rejected claims 1 – 3, 5 - 6, 8, 13 and 15 – 17, the respiration detection of Combs et al. actually teaches away from using the baseline thoracic impedance associated with thoracic fluid shift, and the Combs et al. reference has been misapplied for the proposition that edema in the lungs affects blood pressure. Therefore, Applicant respectfully requests withdrawal of this rejection.

3. Claims 1 – 8, 13 - 20 and 30 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Pitts Crick et al. (U.S. Patent No. 6,104,949). Applicant traverses. Claim 1 has been cancelled, thereby mooting this rejection of that claim. With respect to the other rejected

claims 2-8, 13-20 and 30, Applicant notes that the rejection recognizes that Pitts Crick et al. is directed toward diagnosing and treating congestive heart failure (CHF) by using impedance to detect pulmonary edema. (See Office Action ¶ 5.) However, pulmonary edema refers to fluid accumulation in the lungs. (*See, e.g.,* Combs et al. at column 1, lines 27-36.) By contrast, claims 2-3, 5-8, 15-20, and 30 recite or incorporate providing a therapy to the subject's heart based at least in part on the detected baseline thoracic impedance associated with a fluid shift away from the thorax. Therefore, Pitts Crick et al. does not disclose--and actually teaches away--from the subject matter of claims 2-3 and 5-8.

Likewise, with respect to claim 4, Applicant can find no disclosure in Pitts Crick et al. of increasing a rate of pacing stimuli based at least in part on an increase in the baseline portion of the thoracic impedance. Instead, Pitts Crick et al. discloses detecting the fluid accumulation associated with edema by its associated decrease in thoracic impedance. (*See* Pitts Crick et al. at column 2, line 66 through column 3, line 6.) Therefore, Pitts Crick et al. does not disclose--and actually teaches away from--the subject matter of claim 4.

Regarding claims 13-14, Applicant can find no disclosure in Pitts Crick et al. of detecting both a hypotension associated with a change in a subject's posture and a hypotension that is not associated with a change in the subject's posture, and providing a therapy to the subject's heart based at least in part on the detected hypotension, as recited or incorporated in claims 13-14. The specification of the present patent application notes that hypotension refers to "low blood pressure" or "too-low intravascular fluid tension." (*See* Application at page 2, line 18 and at page 9, line 15.) However, the cited portion of Pitts Crick et al. apparently relates to detecting edema (that is, fluid accumulation) associated with a change in the subject's position. (*See* Pitts Crick et al. at column 2, line 29 through column 3, line 3.) Therefore, Pitts Crick et al. does not disclose--and actually teaches away from--the subject matter of claims 13-14. In view of the above, Applicant respectfully requests withdrawal of this rejection of claims 1 – 8, 13 - 20 and 30.

4. Claims 1– 8, 13 - 20 and 30 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Erlebacher (U.S. Patent No. 6,473,640). Claim 1 has been cancelled, thereby mooting this rejection of that claim. With respect to the other rejected claims 2-8, 13-20 and 30, Applicant notes that the rejection recognizes that Erlebacher is directed toward a device for

detecting and monitoring of CHF and fluid accumulation associated with pulmonary edema (*See* Office Action ¶ 6.) However, because claims 1-8, 13-20, and 30 pertain to fluid shifts away from the thorax, Applicant submits that Erlebacher fails to disclose all elements of these claims, for the same reasons discussed above with respect to Pitts Crick et al. Accordingly, Applicant respectfully requests withdrawal of this rejection.

As an additional note, Applicant notes that the present patent application has a filing date of April 10, 2001, and that Erlebacher did not issue until October 29, 2002. Consequently, Erlebacher is available as prior art (if at all) only under 35 U.S.C. 102(e). Therefore, Applicant does not admit that the cited Erlebacher reference is prior art and reserves the right to "swear behind" Erlebacher as provided for under 37 C.F.R. 1.131.

New Claims

Claims 31-35 have been added to more particularly point out and distinctly claim originally disclosed subject matter. Applicant submits that these claims are allowable, and respectfully requests allowance of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

Applicant has enclosed a check in the amount of $156.00 to cover the fee for adding additional claims. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

AVRAM SCHEINER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
612-373-6951

Date Feb. 10, 2003 By _____
Suneel Arora
Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 10th day of February, 2003.

GREG HANSON _____
Name Signature